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10/698,426	11/03/2003	Lauren D. Johnson	047255-5003-US	6494

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WASHINGTON, DC 20004

EXAMINER
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ROBINSON, KEITH O NEAL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/698,426

Applicant(s)

JOHNSON ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 22-29 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date November 3, 2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's "Response to Restriction Requirement", filed April 6, 2005, has been entered. Applicant elected Invention I, drawn to claims 1-21 and 30, without traverse. Claims 1-21 and 30 are pending and are examined in the instant Office Action.
2. Claims 22-29 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 6, 2005.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

4. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The phrase "about 0.0" makes claim 5, which is dependent upon claim 1, broader than claim 1.

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5. Claims 17 and 19 are objected to for the word "Seed". The claims do not read on a single invention and should be corrected to read - - A seed- - .
6. Claim 30 is objected to the phrase "Alfalfa plants". The claim does not read on a single invention and should be corrected to read - - An alfalfa plant- - .

***Information Disclosure Statement***

7. A third-party submission has been filed under 37 CFR 1.99 on July 30, 2004 in the published application.

To ensure that a third-party submission does not amount to a protest or pre-grant opposition, 37 CFR 1.99 does not permit the third party to have the right to insist that the examiner consider any of the patents or publications submitted. Furthermore, if the submission or part of the submission is not in compliance with 37 CFR 1.99, that noncompliant submission or part thereof will not be entered in the application file. Therefore, unless the examiner clearly cites a patent or publication on form PTO-892, Notice of References Cited and such reference is used in a rejection or its relevance is actually discussed during prosecution, consideration by the examiner of any patent or publication submitted in a third-party submission cannot be presumed.

If the applicant wants to ensure that the information in a third-party submission is considered by the examiner, the applicant should submit the information in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98. An individual who has a duty to disclose under 37 CFR 1.56 should also submit any material information contained in a

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third-party submission to the Office in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98 to ensure such material information is properly disclosed to the examiner.

A third-party submission has been filed under 37 CFR 1.99 on July 30, 2004 in the published application. Applicant is offered an opportunity to file any comments regarding the patents or publications submitted by the third-party submission. Any comments should be filed within the later of the time period set forth in this Office action or one month from the mailing of this Office communication.

***Claim Rejections - 35 USC § 112, second paragraph***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. The term "that is higher than that found naturally" in claim 4 is a relative term which renders the claim indefinite. The term "that is higher than that found naturally" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 112, first paragraph – Written Description***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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11. Claims 1-21 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-21 are broadly drawn to any alfalfa plant with detectable levels of tannins and the seed and pollen of said plant.

The specification does not provide a written description of the genus of alfalfa plants with detectable levels of tannins with regards to their genetic, morphological, and/or physiological characteristics. Only two species, namely CW 28061 and CW 29053, are described in the specification (see page 25, lines 18-29; page 27, Table 4; and page 29, Table 5).

Claim 30 is broadly drawn to any alfalfa plant with improved bloat safety.

The specification does not provide a written description of any alfalfa plant with improved bloat safety in terms of its genetic, morphological, and/or physiological characteristics.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the

absence of knowledge as to what that material consists of, is not description of that material". Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

***Claim Rejections - 35 USC § 112, first paragraph – Enablement***

12. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claim is drawn to an alfalfa plant with detectable levels of tannins wherein the plant is the progeny of one of the parent plants listed in Table 3. Since the parent plant is essential to the claimed inventions, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;



- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,
- (e) the deposit will be replaced if it should ever become inviable.

***Claim Rejections - 35 USC § 112, first paragraph - Enablement***

13. Claims 1-21 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Claims 1-21 are broadly drawn to any alfalfa plant with detectable levels of tannins and the seed and pollen of said plant.

The specification does not teach how to make or use the genus of alfalfa plants with detectable levels of tannins. There is no guidance provided in the specification regarding the genetic, morphological, and/or physiological characteristics of said plant, thus one skilled in the art would not know how to distinguish the claimed alfalfa plant from any other alfalfa plant. There is no guidance provided for the parents that produce the claimed invention in terms of their genetic, morphological, and/or physiological characteristics. Claim 16 makes reference to Table 3 of the specification and the use of the plants in Table 3 as parents, but this list merely lists arbitrary numerical names of parent plants. There is no evidence that any of the listed parents have been used to produce an alfalfa plant with detectable levels of tannins. Thus, it would require undue experimentation for one skilled in the art to screen all the listed parents to determine which, if any, would produce an alfalfa plant with detectable levels of tannins.

Furthermore, there is no guidance in the specification that would allow one of skill in the art to distinguish, for example, an alfalfa plant having a visual staining score that is about 1.0 or higher from another alfalfa plant having the same visual staining score.

Finally, Applicant defines alfalfa as "any *Medicago* species, including, but not limited to, *M. sativa*, *M. murex*, *M. falcata*, *M. prostrata*, and *M. truncatula*" (see page 9, lines 15-16). It is known in the art that all species from a genus will differ in their genetic, morphological, and/or physiological backgrounds. For example Quiros et al (*The Genus Medicago and the Origin of the Medicago sativa Complex*, Chapter 3, pages 93-124, *In*

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Alfalfa and Alfalfa Improvement, Hanson et al (ed.), American Society of Agronomy, Monograph No. 29, 1988) teach that the basic genomic number of *Medicago* is  $x=8$ , but for *M. murex*  $x=7$  (see page 93, section 3-2). In addition, Quiros et al teach that there are three ploidy levels found among the *Medicago* spp (see page 94, second paragraph). Therefore, it would require undue experimentation to select all possible alfalfa plants to determine which, if any, would have detectable levels of tannins as well as cross all possible alfalfa plants, if possible, to produce an alfalfa plant that would have detectable levels of tannins.

Claim 30 is broadly drawn to any alfalfa plant with improved bloat safety.

The specification does not teach how to make and use any alfalfa plant with improved bloat safety. There is no guidance regarding any alfalfa plant with improved bloat safety with regards to its genetic, morphological, and/or physiological characteristics. There is no guidance in the specification that teaches how to recognize the claimed alfalfa plant with improved bloat safety from all other plants with improved bloat safety nor is there any evidence provided in the specification of an alfalfa plant with improved bloat safety. Furthermore, the specification does not provide any guidance as to what would constitute improved bloat safety.

Selecting alfalfa plants for detectable levels of tannins is not predictable. The specification teaches that temperature can play a role in the detection of tannin levels in alfalfa (see page 12, lines 7-8) and that the age of the leaf may make it difficult to determine if an alfalfa plant has a detectable level of tannins (see page 13, lines 3-7). In fact, Bula et al (Crop Sci. 14: 618-621, 1974) teach that repeated sexual propagation of

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an alfalfa synthetic may lead to changes in cultivar characteristics such that subsequent generations would no longer be similar to the original release (see page 618, second column, first paragraph).

Given the lack of guidance regarding an alfalfa plant with detectable levels of tannins and improved bloat safety, the breadth of the claims, and the unpredictability of tannin level detection and sexual propagation of alfalfa, it would require undue experimentation for one skilled in the art to make and use the invention as broadly claimed.

### ***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1 and 4-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Goplen et al (Crop Sci. 20: 801-804, 1980). The claims read on any alfalfa plant with detectable levels of tannins.

Goplen et al disclose alfalfa plants with detectable levels of tannins in seeds (see page 802, second column, third paragraph and page 803, Table 3). Without evidence to the contrary, the plant of Goplen et al inherently has the tannin levels of claims 4-21.

Hence, Goplen et al have previously disclosed all the claim limitations. See *In re*

*Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

16. Claims 2-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Lees (Plant Polyphenols, pp. 915-934, 1992). The claims read on an alfalfa plant having detectable tannin levels in the leaves.

Lees discloses alfalfa plants having levels of tannin in their leaves while in culture (see page 929, third paragraph). Without evidence to the contrary, the alfalfa plant of Lees inherently has condensed tannins in the leaves. Hence, Lees has previously disclosed all the claim limitations. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

17. Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by Coulman et al (Can. J. Plant Sci. 80(3): 487-491, 2000). The claim reads on any alfalfa plant with improved bloat safety.

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Coulman et al disclose a bloat-reduced alfalfa cultivar (see page 489, first column, third paragraph to page 490, first paragraph, end of fourth paragraph).

**Conclusion**

18. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.  
May 9, 2005

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER

